

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The demeclocycline used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(b) The batch for potency and pH.

(ii) Samples required:

(a) The demeclocycline used in making the batch: 10 packages, each containing approximately 250 milligrams.

(b) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Transfer an accurately measured representative portion of the well-shaken suspension to an appropriate-sized volumetric flask and dilute to volume with 0.1*N* hydrochloric acid to obtain a stock solution of convenient concentration containing not less than 150 micrograms of demeclocycline hydrochloride per milliliter (estimated). Mix well. Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 0.100 microgram of demeclocycline hydrochloride per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

[39 FR 19076, May 30, 1974, as amended at 43 FR 11162, Mar. 17, 1978; 43 FR 50677, Oct. 31, 1978; 50 FR 19920, May 13, 1985]

§ 446.115b Demeclocycline for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Demeclocycline for oral suspension is composed of demeclocycline with or without one or more suitable and harmless buffer substances, preservatives, diluents, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains demeclocycline equivalent to 15 milligrams of demeclocycline hydrochloride. Its potency is satisfactory if it is not less

than 90 percent and not more than 120 percent of the number of milligrams of demeclocycline hydrochloride equivalent that it is represented to contain. Its moisture content is not more than 5 percent. The demeclocycline used conforms to the standards prescribed by § 446.15(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The demeclocycline used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The demeclocycline used in making the batch: 10 packages, each containing approximately 250 milligrams.

(b) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Transfer an accurately measured representative portion of the well-shaken suspension to an appropriate-sized volumetric flask and dilute to volume with 0.1*N* hydrochloric acid to obtain a stock solution of convenient concentration containing not less than 150 micrograms of demeclocycline per milliliter (estimated). Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 0.100 microgram of demeclocycline hydrochloride per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19076, May 30, 1974, as amended at 43 FR 11162, Mar. 17, 1978; 50 FR 19920, May 13, 1985]

§ 446.116 Demeclocycline hydrochloride oral dosage forms.

§ 446.116a Demeclocycline hydrochloride tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality,*

and purity. Demeclocycline hydrochloride tablets are composed of demeclocycline hydrochloride with one or more suitable and harmless diluents, lubricants, binders, and flavorings. Each tablet contains 75 milligrams, 150 milligrams, or 300 milligrams of demeclocycline hydrochloride. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of demeclocycline hydrochloride that it is represented to contain. Its loss on drying is not more than 2 percent. It shall disintegrate within 30 minutes. The demeclocycline hydrochloride used conforms to the standards prescribed by § 446.16(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The demeclocycline hydrochloride used in making the batch for potency, loss on drying, pH, absorptivity, crystallinity, and identity.

(b) The batch for potency, loss on drying, and disintegration time.

(ii) Samples required:

(a) The demeclocycline hydrochloride used in making the batch: 10 packages, each containing approximately 250 milligrams.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 0.1N hydrochloric acid to give a stock solution of convenient concentration containing not less than 150 micrograms of demeclocycline hydrochloride per milliliter (estimated). Blend for 3 to 5 minutes. Remove an aliquot of the stock solution and further dilute with sterile distilled water to the reference concentration of 0.100 microgram of demeclocycline hydrochloride per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

[39 FR 19076, May 30, 1974, as amended at 43 FR 11162, Mar. 17, 1978; 50 FR 19920, May 13, 1985]

§ 446.116b [Reserved]

§ 446.116c Demeclocycline hydrochloride capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Demeclocycline hydrochloride capsules are composed of demeclocycline hydrochloride, with one or more suitable and harmless diluents and lubricants, enclosed in a gelatin capsule. Each capsule contains 75 milligrams, 150 milligrams, or 300 milligrams of demeclocycline hydrochloride. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of demeclocycline hydrochloride that it is represented to contain. Its loss on drying is not more than 2 percent, except that if starch is used as a diluent the loss on drying is not more than 8 percent. The demeclocycline hydrochloride used conforms to the standards prescribed by § 446.16(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The demeclocycline hydrochloride used in making the batch for potency, loss on drying, pH, absorptivity, crystallinity, and identity.

(b) The batch for potency and loss on drying.

(ii) Samples required:

(a) The demeclocycline hydrochloride used in making the batch: 10 packages, each containing approximately 250 milligrams.

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing sufficient